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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-594

Approvable Letter (S)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-594

International Medication Systems, Limited
Attention: Mr. Stephen A. Campbell
Vice President, Regulatory Affairs
1886 Santa Anita Ave.
South El Monte, CA 91733

Dear Mr. Campbell:

Please refer to your new drug application (NDA) dated October 31, 2002, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Amiodarone Hydrochloride Injection, 50 mg/ml, 3 ml and 18 ml pre-filled syringes.

We acknowledge receipt of your submissions dated January 9, March 12, April 14, July 21 and August 21, 2003.

We have completed our review of this application, as submitted, with draft labeling, and it is approvable. During a recent inspection of the manufacturing facility for this application, our field investigator conveyed deficiencies to the facility's representatives. Satisfactory resolution to these deficiencies is required before this application may be approved. In addition, you must submit final printed labeling (FPL) revised as follows:

The Syringe Assembly Directions should be moved from the HOW SUPPLIED section to the DOSAGE AND ADMINISTRATION section.

Please submit the final printed labeling (FPL) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format - NDA (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, please contact:

Mr. Russell Fortney
Regulatory Health Project Manager
(301) 594-5311

Sincerely,

{See appended electronic signature page}

DS
Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Doug Throckmorton
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